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10/509,292	09/23/2004	Dimitrios T. Drivas	MP-01	3709

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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,292	DRIVAS, DIMITRIOS T.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *6-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments, filed on November 29, 2007, are acknowledged.

Claims 1-15 are pending.

Claims 6 -15 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claims 1-5 are currently under consideration as they read on the elected invention of a method for treating a subject by generating an active immune response, asthma, SEQ ID NO:16 and Diphtheria toxoid (DT).

2. This Office Action will be in response to applicant's arguments, filed on November 29, 2007.

The rejections of record can be found in the previous Office Action, mailed on May 29, 2007.

3. In view of applicant's amendment to the claims, the prior rejection, under 35 U.S.C. 112, second paragraph, has been withdrawn.

4. In view of applicant's amendment to the claims, the prior rejection, under 35 U.S.C. 112, first paragraph, written description, has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous Office Action mailed on May 29, 2007.

The previous Office Action states:

"The specification as-filed does not enable one skilled in the art to practice the claimed invention without undue amount of experimentation.

The state of the art (Gutierrez-Ramos et al. 1999. Immunology Today. 20;11:500-504 reference on IDS filed on December 22, 2005) recognizes that eotaxin not only induces chemotaxis and migration

of eosinophils and is also a potent initiator of respiratory burst in eosinophils that are recruited and accumulated in the lung during asthma attack (see entire document, particularly page 501).

Similarly, the instant specification discloses that eotaxin can stimulate eosinophil accumulation; in inflammatory conditions e.g. asthma, eotaxin contributes to eosinophil accumulation and degranulation resulting in cell damages (e.g. see pages 5-6 of the instant specification).

The instant claims are drawn to a method for treating a condition mediated by eotaxin via stimulating antibody response to eotaxin; yet eotaxin is the inflammatory mediator. It appears that applicant's method relies upon administering an inflammatory mediator to treat an inflammatory condition. However, the instant specification does not appear to provide sufficient objective evidence that autoantibodies can be generated in such a fashion and even if generated, the autoantibodies would not be neutralized by the existing eotaxin during inflammatory condition; and there is insufficient objective evidence that such autoantibodies would be able to be used for the claimed method of treating a condition mediated by eotaxin. Therefore, it is unpredictable if eotaxin can be administered to treat any condition mediated by eotaxin itself, much less that sufficient autoantibodies can be generated in such manner."

"Further, the specification does not provide sufficient guidance regarding how to make and use a portion of eotaxin, and/or an immunogenic analog of the eotaxin as claimed. Francis et al. (Current Opinion in Allergy and Clinical Immunology 2005. 5:537-543), in addressing peptide-based vaccination, teach that peptides contain little or no secondary or tertiary structure compare to full length proteins; and in certain circumstance, peptides cannot generate specific antibodies against wild type proteins (see entire document, particularly left column on page 540). Further Francis et al. teach the selection of the appropriate peptides for use in immunotherapy remains a challege (see left column on page 514, in particular)."

Applicant's arguments in conjunction with the legal citations have been fully considered but have not been found persuasive.

Applicant argues that the use of vaccines to generate antibodies is a mature art; thus, applicant asserts that the guidance required is not that great. Further, applicant argues that the instant specification provides guidance and exemplification for making the vaccines. Thus, applicant asserts that the rejection should be withdrawn.

This is not found persuasive for following reasons:

The disclosure of the instant specification is not sufficient to enable a skilled artisan to practice the claimed invention without conducting an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Regarding in vivo methods which rely on previously undescribed and generally unpredictable mechanisms, "The amount of guidance or direction needed to enable the invention

is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)." The MPEP also states that physiological activity can be considered inherently unpredictable.

Here, given that eotaxin itself is a inflammatory mediator, it would be unpredictable how a method of treating an inflammatory conditions such as asthma using eotaxin can be practiced. In contrast to applicant's assertion that the instant specification provides detailed guidance, it is noted that the specification has no working example regarding the claimed method.

Further, in Rasmusson v. SmithKline Beecham Corp., 75 USPQ2d 1297-1303 (CAFC 2005), the court states "[W]here there is "no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects," an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement" and "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis."

In this case, given that eotaxin is an inflammatory mediator; eotaxin induces chemotaxis and migration of eosinophils in vivo and in vitro; and accumulation of eosinophils in lung is a main characteristic of asthma (e.g. see Gutierrez-Ramos et al. on page 501), one of skill in the art would not accept without question that eotaxin itself can be used for treating conditions such as asthma.

With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

Therefore, applicant's arguments have not been found persuasive and the rejection is maintained.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald et al. (WO 00/04926) for reasons of record set forth in the previous Office Action mailed on May 29, 2007.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that the prior art eotaxin is intended to be used as ligand and the prior art further teaches that eotaxin conjugated with toxins. Applicant further asserts that the claimed eotaxin is to be used as immunogenic conjugates. Thus, applicant asserts that the prior art does not anticipate the claimed method.

This is not found persuasive for following reasons:

The reference teaches a method of treating conditions such as asthma by administering the same eotaxin as claimed. Although the reference is silent about generating autoantibodies, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

In this case, it is reasonable to conclude that the same patient is being administered the same eotaxin by the same mode of administration in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Therefore, applicant's arguments have not been found persuasive.

9. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Bachmann et al. (US 2003/0157479) for reasons of record set forth in the previous Office Action mailed on May 29, 2007.

It is noted that although the statues of 35 U.S.C. 102(e) is cited on page 9 of the Office Action mailed on May 29, 2007, the rejection based on Bachmann et al. (US 2003/0157479) was made under 102(b) because of an inadvertent typographic error. As applicant acknowledged that Bachmann et al. (US 2003/0157479) has the priority date of November 7, 2001 and the instant application claims priority to March 25, 2002, Bachmann et al. (US 2003/0157479) would be qualified as 102(e) type of reference. The Examiner apologizes for any inconvenience related to this issue.

The previous Office Action states:

"Bachmann et al. teach methods of treating diseases such as asthma in a subject such as human by immunizing said subject with a composition comprising antigenic determinant of proteins including eotaxin peptide fragments conjugated to a protein carrier (see entire document, particularly Detailed Description of the Invention on paragraphs [0054]-[0086])."

Given the absence of additional rebuttal to the rejection of record in applicant's amendment, the rejection is maintained for reasons of record.

10. Conclusion: no claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle (formerly Chun Crowder)
Patent Examiner
January 19, 2008

/Maher M. Haddad/
Primary Examiner, Art Unit 1644